April 12, 2024

MicroPort Orthopedics, Inc.
Hunter Williams
Manager, Regulatory Affairs
5677 Airline Road
Arlington, Tennessee 38002

Re: K240452
Trade/Device Name: Ceramic Femoral Head
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip Joint Metal/Ceramic/Polymer Semi-Constrained Cemented Or Nonporous Uncemented Prosthesis
Regulatory Class: Class II
Product Code: LZO
Dated: February 15, 2024
Received: February 15, 2024

Dear Hunter Williams:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Limin Sun -S

Limin Sun, Ph.D.
Assistant Director
DHT6A: Division of Joint
Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240452

Device Name

Ceramic Femoral Head

Indications for Use *(Describe)*

MicroPort total hip systems are intended for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

1. non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. inflammatory degenerative joint disease such as rheumatoid arthritis;
3. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) Summary of Safety and Effectiveness

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a Summary of Safety and Effectiveness for the Ceramic Femoral Head.

Submitted by:	MicroPort Orthopedics Inc. 5677 Airline Rd, Arlington TN, 38002 USA Phone: 901-451-6511 Fax: 855-446-2247
Date:	April 12, 2024
Contact Person:	Hunter E. Williams, Manager, Regulatory Affairs
Proprietary Name:	Ceramic Femoral Head
Common Name:	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Classification Name and Reference:	21 CFR 888.3353 – Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented Or Non-Porous, Uncemented Class II
Subject Product Code and Panel Code:	Orthopedics/87/ LZO
Primary Predicate Device:	**BIOLOX delta Option and Extra-long Heads** (K173776)
Predicate Devices:	**Signature Ceramic Femoral Head** (K190704) **MicroPort Orthopedics Total Hip Systems MR Labeling** (K173898)

MicroPort Orthopedics

DEVICE INFORMATION

A. **Intended Use/Indications for Use Statement**

MicroPort total hip systems are intended for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

1. non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. inflammatory degenerative joint disease such as rheumatoid arthritis;
3. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed.

B. Device Description

The modular Ceramic Femoral Head is composed of alumina matrix composite, manufactured as per ISO 6474-2. It has a 12/14 taper which is identical to the taper on MicroPort Orthopedics' range of femoral heads. The device articulates with an acetabular liner and is compatible for use across any of MicroPort Orthopedics' total hip component range.

C. Substantial Equivalence Information

The indications for use for MicroPort Orthopedics' Ceramic Femoral Head (CoorsTek) remain the same as the indications for use for the MicroPort Orthopedics' Femoral Head (CeramTec) and subject device shares the same indications for use as the Signature Orthopaedics' Signature Ceramic Femoral Head.

The ceramic femoral head (Permallon Tru) manufactured by CoorsTek has the same geometry as the previously cleared ceramic femoral head (Biolox delta) manufactured by CeramTec with identical conical bore which is a 12/14 taper that can accept a MicroPort trunnion having 12/14 taper, in the form of either a monolithic classic hip stem or modular femoral neck.

The femoral head offset and gauge diameter, taper, bore angle, bore straightness, bore surface roughness, articulating surface roughness, sphericity and defect requirements are identical to the predicate device. There are no significant differences in these technological characteristics between the subject and predicate devices affecting performance or safety.

The only difference compared to the predicate femoral head (BIOLOX delta) is the manufacturing of the Ceramic Femoral Head from alumina matrix composite (Permallon Tru) provided by CoorsTek.

D. Nonclinical Testing

Engineering evaluations were conducted to verify that the performance of the Ceramic Femoral Head manufactured from alumina matrix composite (Permallon Tru) is equal to and/or better than the predicate device and therefore adequate for the anticipated in-vivo use. The following V&V activities were conducted:

- Axial compression test
- Fatigue test
- Post-fatigue ultimate compression strength test
- Static pull off test
- Static torsion test
- MR Safety Evaluation per ASTM F2182-19 and FDA Guidance for "Assessment of Radiofrequency-Induced Heating in the Magnetic Resonance (MR) Environment for Multi-Configuration Passive Medical Devices" issued March 2016, ASTM F2052-21, ASTM F2119-07 (reapproved 2013). Results were compared to non-predicate benchmarks.

Non-clinical (mechanical) testing results met the applicable acceptance criteria; therefore, acceptable mechanical performance is expected of the Ceramic Femoral Head manufactured by CoorsTek. Based on comparability of mechanical performance data, the subject device is substantially equivalent to the predicate devices.